AMERICAN LUNG ASSOCIATION.

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March 28, 2019

Mr. Aaron Yeow, Designated Federal Officer (DFO)
EPA Science Advisory Board Staff Office (1400R)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460

Re: Comments on the Clean Air Scientific Advisory Committee's draft review of the EPA's Integrated Science Assessment (ISA) for Particulate Matter (External Review Draft—October 2018).

Dear Mr. Yeow:

The American Lung Association appreciates the opportunity to provide comments on the CASAC's draft comments on their review of the ISA for Particulate Matter.

The review of the National Ambient Air Quality Standards (NAAQS) for particulate matter (PM) is a top priority concern for the protection of public health, a position reinforced by the escalating evidence of its widespread harm. For decades, the American Lung Association has closely followed and participated in the reviews of the research into the health effects of the criteria pollutants. The Lung Association has generally supported the CASAC in its reviews, valuing the thoughtful insights and careful questions that the members raised to provide to EPA the strongest scientific basis for its decisions about the NAAQS. The core purpose under the Clean Air Act for this process is crucial: to set air quality standards that protect public health with an adequate margin of safety.

The importance of this task makes this Committee's draft response to the PM ISA especially troubling. Of greatest concern is the effort by some of the Committee to dismiss the long-established protocol for determining causality.

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Two of the comments on the first page are incorrect and should be removed:

- The claim that there is no "comprehensive or systematic assessment of the science" despite nearly 1900 pages that examine in depth more than 2,000 studies.
- The claim that the ISA does not "follow widely accepted scientific methods for deriving . . . conclusions" when the ISA follows the process used by other scientific organizations to determine causality in their reviews and followed for years by prior CASACs.

This draft letter's exaggerated, inaccurate arguments about process and rationale for determining causality misrepresents the structured, reasoned approach that the CASAC has historically followed and that the EPA staff followed in compiling this assessment.

This ISA clearly explains the careful approach to determining causality in the Preface. This approach has been in place for ten years, adopted to follow the process used by the National Academy of Sciences, as well as the Centers for Disease Control and Prevention, among others, to determine causality. The process provides a structured, transparent framework to determine what the thorough analysis of myriad studies adds to the knowledge about the health impacts of these pollutants. That framework incorporates questions on the issues of possible confounding elements, toxicological evidence, and consistency in the outcomes.

Instead, this Committee's draft letter proposes to redesign that process arbitrarily and without peer-review by the scientific community or even EPA's own Science Advisory Board. The approach proposed here would seek to replace the well-established method with a novel one that lacks evidence of similar review, much less evidence of effectiveness in its outcomes. Worse, that new approach would seem to allow the reviewers to dismiss any evidence that health outcomes improve with lower pollution simply because they fail to meet the unvetted, alternative causation criteria.

The ISA analyzes more than 2,600 studies examining complex aspects of the growing research in particulate matter. The sheer volume of new research since the 2009 ISA demonstrates the importance and complexity of the questions. Not only does the document explore the differences in sources, composition, and size of the particles, the ISA examines the studies that explore their impact on the respiratory, cardiovascular, neurological, and reproductive and development systems as well as premature mortality. The ISA examines the toxicological mechanisms that may account for or contradict such potential impacts.

The current approach recognizes that uncertainty in scientific research exists. It always has. However, it seeks to assess the abundant information systematically with established questions to best determine what we know now. The Clean Air Act recognizes that achieving absolute knowledge about all the health effects of these pollutants at any time is unrealistic. That is why the Act directs EPA to review the science every five years and to set the standards to truly protect public health by building in "an adequate margin of safety."

One of the outcomes of using this new, unvetted causality approach is the lack of agreement within the CASAC members about the long-established conclusion that particulate matter causes premature mortality. The evidence for this began in real-world examples in Donora, Pennsylvania in 1948[1] and in London in 1952,[2] but came into full scientific review 25 years ago when the

Harvard Six Cities and the American Cancer Society studies found rigorous evidence that breathing particulate matter shortens life.[3] The Health Effects Institute, an organization jointly funded by EPA and the automobile industry, reviewed the raw data and supported the conclusions in 2001.[4] Since then, numerous other studies, using different databases, as well as others following up on these landmark studies, have consistently found that particulate matter kills people.[5] Prior CASACs and their expert panels have all reached the same conclusion.

The Lung Association finds the inability of some CASAC members to recognize this established conclusion disturbing. This lack of a decision in the face of such well-vetted reviews offers profound evidence that, at the very least, the CASAC needs the expert advice from epidemiologists, additional toxicologists, physicians, ecologists and other scientists.

We agree with the Committee that the members desperately need the assistance of the PM expert panel that had been working with the prior CASAC to develop the plan for this review and to assist in assessing the science. As we noted in our comments in December, no seven people could be expected to review and assess this much information alone, especially lacking key experience in epidemiology and other expertise for this review.

In December, the Lung Association provided recommendations for improvements to the ISA. We again urge EPA to reinstate the former PM panel to assist this Committee to better review these studies. We support CASAC's request for a second draft; however, that revised draft should use the current causality review and incorporate the changes from our earlier comments and the added input from the reconstituted panel. Most critically, we urge this Committee to recognize that the overall approach and thorough review of the studies in this ISA is fundamentally sound.

We note that, fortunately, some CASAC members clearly disagreed with the draft conclusions included in the Committee's draft letter. The Lung Association strongly urges the CASAC to reconsider and revise the comments to EPA on this Integrated Science Assessment.

Sincerely,

Albert Rizzo, MD,
Chief Medical Officer

[1] Jacobs ET, Burgess JL, and Abbott MB. The Donora Smog Revisited: 70 Years After the Event That Inspired the Clean Air Act. *Am J Pub Health*. 2018 April; 108(Suppl 2): S85–S88.
[2] Scott JA. Fog and deaths in London, December 1952. *Public Health Rep.* 1953 May; 68(5): 474–479; Bell ML and Davis DL. Reassessment of the lethal London fog of 1952: novel indicators of acute and chronic consequences of acute exposure to air pollution. *Environ Health Perspect.* 2001 Jun;109 Suppl 3:389-94.
[3] Dockery DW, Pope CA III, Xu X, Spengler JD, Ware JH, Fay ME, Ferris BG, Speizer FE. An association between air pollution and mortality in six U.S. cities. *N Engl J Med.* 1993; 329: 1753-1759. Pope CA, Thun MJ, Namboodiri MM, Dockery DW, Evans JS, Speizer FE, Heath CW. Particulate air pollution as a predictor of mortality in a prospective study of U.S. adults. *Am J Respir Crit Care Med.* 1995; 151: 669-674.
[4] Health Effects Institute. Special Report: Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality. 2000.
[5] Di Q, Wang Y, Zanobetti A, et al. Air Pollution and Mortality in the Medicare Population. *NEJM.* 2017; 376:2513-2522; Di Q, Dai L, Wang Y, Zanobetti A, Choirat C, Schwartz JD, Dominici F. Association of Short-Term Exposure to Air Pollution with Mortality in Older Adults. *JAMA.* 2017; 318: 2446-2456; Correia AW, Pope CA III, Dockery DW, Wang Y, Ezzati M, Domenici F. Effect of air pollution control on life expectancy in the United States: An analysis of 545 U.S. Counties for the period from 2000 to 2007. *Epidemiology*. 2013; 24(1): 23-31; Lepeule J, Laden F, Dockery D, Schwartz J. Chronic exposure to fine particles and mortality: An extended follow-up of the Harvard Six Cities Study from 1974 to 2009. *Environ Health Perspect.* 2012; 120: 965-970; Ostro B, Broadwin R, Green S, Feng WY, Lipsett M. Fine particulate air pollution and mortality in nine California counties: results from CALFINE. *Environ Health Perspect.* 2006: 114: 29-33; Ostro B, Feng WY, Broadwin R, Malig B, Green S, Lipsett M. The Impact of Components of Fine Particulate Matter on Cardiovascular Mortality in Susceptible Subpopulations. *Occup Environ Med.* 2008; 65(11): 750-6. This list is not intended to be comprehensive.